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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/795,790	03/08/2004	Arindam Roy	NVI 5268.2	7703
321	7590	06/21/2006	EXAMINER	
SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			SAUCIER, SANDRA E	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/795,790

Applicant(s)

ROY ET AL.

Examiner

Sandra Saucier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Continuation of Disposition of Claims: Claims pending in the application are 1-5,14,17,18,21-24,26,34,36,41,45,50,56-58,66-68,73,77,82,88,92,96,97,101,102,106,113,114,120,126,130,134,145-147,150-152 and 155-187.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-5,14,17,18,21-24,26,34,36,41,45,50,56-58,66-68,73,77,82,88,92,96,97,101,102,106,113,114,120,126,130,134,145-147,150-152 and 155-187.

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Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1–5, 14, 17, 18, 23, 24, 26, 34, 36, 41, 45, 50 drawn to a first process, a process of resolving an enantiomeric mixture of the α -hydroxy acid ester of claim 1 using a specific lipase from various sources, classified in class 435, subclass 280.
- II. Claims 21 and 22, drawn to a second process, a process of making an enzymatic catalyst, classified in class 435, subclasses various depending on enzyme.
- III. Claims 56–58, 66–68, 73, 77, 82, 88, 92, 96, 97, 101, 102, drawn to the product of the process of Group I, classified in class various, subclasses various depending on the product.
- IV. Claim 106, drawn to a third process, a method of use of the product of Group III, classified in class 426, subclass 1+, depending on the product.
- V. Claims 113, 114, 120, 126, 130, 134, 145, 146, drawn to a fourth process, a process for producing an α -hydroxy acid ester and resolving the resultant mixture using an enantioselective enzyme, classified in class 435, subclass 280.
- VI. Claims 147, 150–152, drawn to a fifth process, a process for producing an α -hydroxy acid ester and continuously resolving the resultant mixture with an immobilized enantioselective enzyme, classified in class 435. subclass 280.
- VII. Claims 155–157, drawn to a sixth process, a process for resolving an enantiomeric mixture of the α -hydroxy acid ester of claim 155 comprising using a heterogeneous catalyst containing an

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immobilized enantioselective enzyme, classified in class 435, subclass 280.

- VIII. Claims 158–173, drawn to a seventh process, a process for resolving mixtures of α -hydroxy acids comprising contacting the esters with an enantioselective enzyme, classified in class 435, subclass 280.
- IX. Claims 174–187, drawn to the product of the process of Group VIII, classified in class various, subclass various depending on the product.

The inventions are distinct, each from the other because of the following reasons: The processes I, II, IV, V, VI, VII, VIII are distinct from one another because they recite different and distinct steps which require different and distinct starting products or intermediate products. For example, the process of Group I requires specific lipases which are not required by the processes of Groups II, IV, V, VI, VII or VIII. The process of Group II is directed to the formation of an enzymatic catalyst which leads to a distinct end product from the processes of Groups I, IV, V, VI, VII and VIII. The process of Group IV is a method of use of the product of Group I and therefore, has distinct steps from the processes of Groups I, II, V, VI, VII and VIII. Group V requires the production of an α -hydroxy ester and therefore requires distinct starting products from the processes of Groups I, II, IV, VII and VIII. Group VI requires distinct materials from Groups I, II, IV, V, VII and VIII because it requires an immobilized enzyme which is not required in the methods of Groups I, II, IV or VIII. Group VIII requires distinct materials from Groups I, II, IV, V, VII because it requires a homogeneous immobilized enzymatic catalyst not required by the other processes.

Inventions I and III and inventions VIII and IX are related as processes of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make

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another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case (2) the product may be made by physically mixing the required compounds.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product such as D-lactic acid may be used as an intermediate in production of polymeric polylactides.

The several inventions listed above are independent and distinct from one another as they have acquired a separate status in the art and require independent searches, particularly with regard to the literature searches. Clearly, a reference which would anticipate one of the above groups would not necessarily anticipate or even make obvious any of the others.

An undue burden would ensue from the examination of multiple methods which have distinct steps and end points. Burden lies not only in the search of US Patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, clarity and enablement.

Clearly a reference which makes obvious or anticipates one Group would not necessarily make obvious or anticipate another Group. If applicant disagrees with this statement, an admission of the obviousness of the groups over one another on the record would allow rejoinder of at least some of the groups.

In addition if Group I, III, IV, V or V is elected, a further election of species must be made.

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If Group I, III, IV or VII is chosen, a substituent from R1 and R2 must be further chosen.

If Group VIII, or IX is chosen, a specific acid from glycolic, lactic, glyceric, tartaric, citric, glyoxylic, pyruvic, malic, benzilic, α -hydroxy analogs of asparagine, alanine, valine, isoleucine, phenylalanine, proline, serine, threonine, cyteine, methionine, tryptophan, tyrosine, glutamine, aspartic, glutamic, lysine, arginine or histidine must be further chosen.

If Group V is chosen, a specific acid from glycolic, lactic, glyceric, tartaric, citric, glyoxylic, pyruvic, mandelic, malic, benzilic, α -hydroxy analogs of asparagine, glycine, alanine, valine, leucine, isoleucine, phenylalanine, proline, serine, threonine, cyteine, methionine, tryptophan, tyrosine, glutamine, aspartic, glutamic, lysine, arginine or histidine must be further chosen.

The above are directed to patentably distinct species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and ***a listing of all claims readable thereon***, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

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retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized, cursive script.

Sandra Saucier
Primary Examiner
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June 16, 2006